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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,755	10/30/2001	Toshihiro Shimizu	2522 US2P	1478

23115 7590 06/15/2004

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,755	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,9,11-19,21-29 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,9,11-19,21-29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/07/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Amendment and Information Disclosure Statement filed 03/08/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5, 7, 9, 11, 12, 15-19, 21, 22, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Lundberg US 6,132,770.

Lundberg teaches an effervescent tablet comprising mixture of enteric-coated pellets (beads, particles, granules) containing proton pump inhibitor (ppi) core (acid-labile active substance) (column 3, lines 59 through column 4, lines 1-19). The core material is chosen from celluloses, sugar, non-pareils, or mixture thereof, having size of

0.1-4 mm (100-4000 μm) (column 8, lines 11-54). The ppi is mixed with filler, binder, lubricant, disintegrant, surfactant, other additives, and alkaline reacting agent (basic salt), including, calcium and magnesium salts (column 8, lines 55 through column 9, lines 1-5). The filler, binder, lubricant, disintegrant, surfactant, and other additives, including sodium lauryl sulfate, microcrystalline cellulose, mannitol, and hydroxypropyl cellulose are disclosed in column 22, lines 53-57). The pellets are coated with one or more enteric coating layers comprising methacrylic acid copolymers, and an over coating layer (column 10, lines 16 through column 11, lines 1-21). The coated pellets are then compressed to tablets having hardness of 51-100 N (which if converted into kg would fall within the claimed range), and disintegrating time is about 55 seconds (see examples).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 7, 9, 11-19, 21-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg US 6,132,770.

Lundberg is relied upon for the reasons stated above. Lundberg does not teach the content of hydroxypropoxyl group in the hydroxypropyl cellulose as claimed in

claims 27 and 28. However, Lundberg teaches the use of hydroxypropyl cellulose within the claimed amount (examples 5, 6, 8, and 12) to obtain the same result, namely, an effervescent (disintegrable) tablet having the claimed hardness and disintegrating time. Accordingly, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable hydroxypropoxyl group of the hydroxypropyl cellulose to obtain the claimed invention, because the reference teaches the use of a similar compound to achieve the claimed tablet having the desired hardness and disintegration time.

It is noted that Lundberg does not expressly teach the claimed amounts of the ingredients of claims 14-16. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 03/08/04 have been fully considered but they are not persuasive.

Claims 1-3, 5, 7, 9, 11, 12, 15-19, 21, 22, 29 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Lundberg US 6,132,770.

Applicant argues that the effervescent tablet taught by Lundberg dissolve in a glass of water, not in a patient's mouth. Applicant further argues that the effervescent time of the tablet in Lundberg is not an oral disintegration time. In response to applicant's argument, it is the position of the examiner that the oral disintegration time is inherent because Lundberg teaches an effervescent tablet comprising similar ingredients that exhibit similar result desired by the applicant, *e.g.*, effervescent dosage form that is especially suitable for patients with swallowing disorders and in pediatrics (column 3, lines 52-54). It is noted that when the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Applicant argues that Lundberg does not teach the second component, the sustained release agent. Contrary to the applicant's argument, first, the claimed has not defined the sustained release agent. Secondly, applicant's attention is called to column 10, lines 20-25, where Lundberg discloses one or more enteric coating layers are

applied onto the core, and wherein the enteric coating layer comprises one or more or combination of polymers, including methacrylic acid copolymers. Accordingly, Lundberg does teach the second component.

Claims 1-3, 5, 7, 9, 11-19, 21-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg US 6,132,770.

Applicant argues that the claimed invention is not obvious over Lundberg because Lundberg does not teach an effervescent tablet that dissolves in a patient's mouth, but rather, in water. Applicant further argues that the effervescent time of the tablet in Lundberg is not an oral disintegration time. According to the above argument regarding to the 102(e) rejection, the burden is shifted to applicant to provide a side-by-side data showing the effervescent tablet taught by Lundberg does not dissolve in a patient's mouth in less than 1 minute.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER
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